Veterinary Medicines Directorate

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Post Authorisation Assessments

Butagran Equi 200 mg/g Oral Powder for Horses

Vm 28365/4004

•	20 September 2023	Replacement of a primary packaging site of a non-sterile finished product (GB).
•	04 October 2018	Change in RMS from UK to BE.
•	15 March 2018	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Submission of an updated Ph. Eur. certificate of suitability
•	11 January 2018	Renewal UK as RMS.
•	15 August 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	09 December 2015	Submission of an updated certificate of suitability.
•	2 December 2015	Approval of revised mock-up for 100 x 5g outer carton presentation.
•	4 September 2014	Addition of a new pack size of the finished product – 20 sachets.
•	15 August 2014	To extend the shelf life of the finished product, from 18 months to 36 months.
•	15 May 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	17 October 2013	Change to the composition (excipients) of the finished product.